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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,882	12/19/2001	Sheldon Tobe	PT-1949001	8815

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/020,882	TOBE, SHELDON
	Examiner	Art Unit
	JOHN PAK	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *2-8,11-13,15,16 and 18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/19/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Claims 18-23 have been added. Claims 1-23 are now pending in this application.

Newly submitted claims 18-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. While the originally claimed invention required the presence of at least sodium, magnesium, chloride and bicarbonate, new claims 18-23 only require bicarbonate. The new claims read on dialysis concentrates and dialysis solutions that do not contain all of sodium, magnesium, chloride and bicarbonate. In the dialysis concentrate and dialysis solution art, such differences in composition content and makeup are significant and sufficient for distinctness and independence. Applicant's original claims are ample evidence of this – applicant asserted patentability based on the fact that the composition contains low bicarbonate, with NaCl, $MgCl_2$, and $NaHCO_3$ at specific concentrations (original claim 1, calcium could be present therein), or no calcium and low bicarbonate, with Na, Mg and Cl (original claim 14). The compositions of claims 18-23 are therefore distinct and/or independent from the compositions of originally presented and examined claims 1, 9-10, 14 and 17.

Since applicant has received an action on the merits for the originally presented and elected invention, this invention has been constructively elected

over the newly submitted claimed invention by original presentation for prosecution on the merits. Accordingly, claims 18-23 are withdrawn from consideration as being directed to a non-elected invention.. See 37 CFR 1.142(b) and MPEP § 821.03.

Additionally, claims 2-8, 11-13 and 15-16 stand withdrawn from further consideration as being directed to non-elected subject matter. See the restriction requirement of 7/13/2004 and applicant's election of 8/10/2004.

In sum, claims 2-8, 11-13, 15-16 and 18-23 are withdrawn from further consideration, and claims **1, 9-10, 14 and 17** will presently be examined to the extent that they read on the elected subject matter.

The following is a quotation of the second paragraph of 35 USC 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment of claim 1 resulted in the following claim language, "a concentration of **bicarbonate sodium bicarbonate**(NaHCO3) ...." (emphases added). Dependent claims 9-10 do not fully clear up what the emphasized substance is. The claims are therefore confusing and unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United states before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9, 14 and 17 are rejected under 35 USC 102(b) as being anticipated by Purcell et al. (US 5,945,449).

Purcell et al. explicitly disclose a sterile calcium-free bicarbonate concentrate comprising 86.87 ± 8.6 g/l NaCl, 2.05 ± 0.2 g/l $MgCl_2$, and 39.69 ± 3.9 g/l $NaHCO_3$ (column 4, lines 52-56). A sterile, diluted solution is also disclosed, wherein 140 ± 14 mM Na, 0.75 ± 0.07 mM Mg, 106.5 ± 10 mM Cl, and 35 mM ± 3.5 HCO_3 are present (column 4, lines 59-63). The concentrate is used in the field of peritoneal dialysis and hemodialysis (column 4, lines 66-67).

It is clearly recognized by the Examiner that instant claim 1 recites, "concentration of bicarbonate [ ] sufficiently low so as to allow preparation of a sterile dialysis solution having a bicarbonate concentrate of 5-30 mmol/l." The claim language in independent claims 14 and 17 is similar in that the concentrate

is formulated such that the resulting dialysis solution has a bicarbonate level within the range of 5-30 mmol/l.

However, it must also be recognized that applicant's claims 1, 9, 14 and 17 are directed either to the concentrate per se or a diluted form without any further specificity as to composition makeup. Even though Purcell et al. did not actually dilute their concentrate so that it resulted in 5-30 mM HCO_3, Purcell's concentrate is inherently capable of being so diluted. Any bicarbonate-containing concentrate can allow the diluted form to have 5-30 mM HCO_3. This is a necessary property of the concentrate and it cannot be somehow extinguished by the actual diluted solution obtained by Purcell et al. Therefore, since Purcell's sterile, calcium-free concentrate contains 39.69 ± 3.9 g/l $NaHCO_3$, said concentrate would necessarily have been capable of being diluted to provide a solution that contains 5-30 mM HCO_3.

The claim language pertaining to minimizing risk to metabolic complications and continuous renal replacement therapies such as dialysis and hemofiltration are noted, but since Purcell's composition contains the same composition ingredients or composition ingredients that cannot be distinguished from applicant's claimed composition, and since Purcell's composition is suitable for hemodialysis and peritoneal dialysis, such properties would have been necessarily present in Purcell's composition. MPEP 2112, 2112.01.

All of applicant's claim features are thereby met. The claims are anticipated.

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Mahiout (US 6,492,336).

Upon reconsideration, it has been determined that Mahiout is applicable against claim 17.

Mahiout explicitly discloses a peritoneal dialysis solution that contains the following anions and cations (see claim 18 in view of claim 1):

125-140 mEq/l of sodium;

90-125 mEq/l of chloride;

1-5 mEq/l of calcium;

0.2-5 mEq/l of magnesium; and

25-40 mEq/l of a buffering anion selected from the group consisting of lactate, pyruvate and bicarbonate.

Sterilization of the solution and use of sterile, pyrogen free water are explicitly taught (column 8, lines 43-51; column 10, lines 42-54).

Applicant's claim 17 is directed to a sterile dialysis concentrate for use in the preparation of a dialysis solution. Calcium free feature is not recited in claim 17. There is nothing about Mahiout's dialysis solution that prevents it "for use in the preparation of a dialysis solution." The use could simply be performing peritoneal dialysis with Mahiout's solution. Designation of "concentrate" does not provide sufficient distinguishing weight to applicant's claim because there is no specific dilution factor claimed. 25 mEq bicarbonate/l is low enough to meet applicant's bicarbonate feature.

The claim language pertaining to minimizing risk to metabolic complications is noted, but since Mahiout's composition contains the same composition ingredients or composition ingredients that cannot be distinguished from applicant's claimed composition, and since Mahiout's composition is suitable for peritoneal dialysis, such property would have been necessarily present in Mahiout's composition.

Claim 17 is thereby anticipated.

Claims 14 is rejected under 35 USC 102(b) as being anticipated by Koo et al. (previously cited as Chemical Abstracts 124:325351; full article is cited herein).

Koo et al. explicitly disclose a calcium-free dialysate, which contains 135 mM sodium, 2.5 mM potassium, 108 mM chloride, 0.75 mM magnesium, and 30 mM bicarbonate, at pH 7.8 (page 425, left column, third full paragraph). Calcium-free hemodialysis was performed (page 425, left column).

Applicant's claim 14 is directed to a sterile calcium free, low bicarbonate dialysis concentrate. The sterile feature would have been necessarily present in a dialysate for hemodialysis. Applicant's designation of "concentrate" does not provide sufficient distinguishing weight to claim 14 because there is no specific dilution factor claimed. Given that the same exact composition ingredients are present in Koo's dialysate, the same properties must necessarily be present. The claim is thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9-10, 14[1] and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koo et al.

Koo et al. disclose calcium-free hemodialysis for treating hypercalcemia (page 425, left column, first full paragraph). Koo et al. used a commercially available calcium-free dialysate, which contained 135 mM sodium, 2.5 mM potassium, 108 mM chloride, 0.75 mM magnesium, and 30 mM bicarbonate, at pH 7.8 (page 425, left column, third full paragraph).

Applicant's independent claims 1 and 14 are directed to a sterile calcium free, low bicarbonate concentrate. Independent claim 17 is similar, but it does not require the calcium free feature. The sterile feature would have been necessarily present in a dialysate for hemodialysis. Further, one having ordinary skill in the art would have been motivated to provide a sterile dialysis concentrate or solution in order to ensure patient safety. Applicant's designation of "concentrate" does not provide sufficient distinguishing weight because there is

[1] Inclusion of claim 14 in this section 103 ground of rejection reflects an interpretation of claim 14 that includes some dilution factor.

no specific dilution factor claimed. Even if there were a specific dilution factor claimed, one having ordinary skill in the art would have been motivated to first formulate a concentrate and then dilute the concentrate to the component concentration disclosed and suggested by Koo et al., because concentrates provide the advantage of storage stability and convenience.

Koo et al. do not specifically disclose that present in their dialysis solution are NaCl, $MgCl_2$, and $NaHCO_3$ (based on one interpretation of the confusing claim 1 that it requires $NaHCO_3$). Koo et al. only disclose that Na, Cl, Mg, HCO_3 and K ions are present, with no explicit disclosure as to the specific compounds that dissociated to provide such ions. However, choice of NaCl, $MgCl_2$ and $NaHCO_3$ would have been obvious to the ordinary skilled artisan because those compounds naturally function as the source of the required ions.

It is noted that dependent claim 10 requires the HCO_3 concentration in the resulting dialysis solution to be 25.0 ± 2.5 mM. Hence, the highest HCO_3 concentration readable on claim 10 is 27.5 mM. The commercial calcium-free dialysate that Koo et al. used has an HCO_3 concentration of 30 mM. One having ordinary skill in the art would have recognized that Koo et al. used a commercial calcium-free dialysate that had a certain content of ions for hemodialysis of hypercalcemic patients. The criticality in Koo's studies is in the calcium free feature, since plasma calcium is monitored for hypercalcemic patients (pages 425-26, "Results" section). Therefore, given Koo's disclosure of 30 mM HCO_3 at pH 7.8, one skilled in the art would have been motivated to modify the HCO_3

concentration slightly and still expect successful treatment of hypercalcemia. In the event that the commercial dialysate product that Koo et al. used is not available to the ordinary skilled artisan in this field, he/she would have been motivated to formulate his/her own dialysate concentrate or solution that provided similar ion content and makeup. Since the criticality in following the teachings of Koo et al. is in the calcium-free feature, slight modification of HCO_3 content, such as within 27.5 mM, would have been suggested and expected to provide therapeutic dialysis treatment to hypercalcemic patients.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited reference.

Claims 1, 9, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martis et al. (WO 96/01118) in view of Purcell et al.

Martis et al. disclose a peritoneal dialysis solution that comprises:

Dextrose	1.5-4.25 g/dl
Na	100-140 mEq/l
Cl	70-110 mEq/l
Calcium	0.0-4.0 mEq/l
Mg	0.0-4.0 mEq/l
Bicarbonate	20.0-30.0 mEq/l
Weak acid	10-20 mEq/l.

See Martis' claim 7.

Applicant's calcium free feature is met by Martis' clear teaching of 0.0 mEq/l of calcium. Martis' 20-30 mEq/l bicarbonate concentration is expressly within applicant's concentration range. A sterile concentrate or solution is not explicitly disclosed by Martis et al. However, one having ordinary skill in the art would have been motivated to provide a sterile dialysis solution in order to ensure patient safety. Applicant's designation of "concentrate" does not provide sufficient distinguishing weight because there is no specific dilution factor claimed. Even if there were a specific dilution factor claimed, one having ordinary skill in the art would have been motivated to first formulate a concentrate and then dilute the concentrate to the component concentration disclosed and suggested by Martis et al., because concentrates provide the advantage of storage stability and convenience.

Further, the patent by Purcell et al. (US 5,945,449) is cited to establish that one having ordinary skill in the art would have been well aware of the benefit of using a sterile peritoneal dialysis solution, which is obtained from a sterile dialysis concentrate. See from column 4, line 64 to column 5, line 7.

While the composition makeup in Purcell et al. is different, their disclosure establishes that the level of the ordinary skill in this art would have been such that sterile dialysis concentrate and sterile dialysis solution would have been well within the skill of the ordinary skilled artisan.

Consequently, the ordinary skilled artisan would have been motivated to utilize a sterile dialysis concentrate and prepare a sterile dialysis solution in accordance with Martis' disclosure (e.g., claim 7).

Additionally, because Martis' dialysis solution is biochemically balanced to correct metabolic acidosis (page 4, lines 7-10), applicant's feature of minimizing metabolic complication risks is met. As for the feature of "for continuous renal replacement therapies such as dialysis and hemofiltration," the composition makeup of Martis' dialysis solution and the concentrate suggested thereby would be suitable for such therapies.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.[2]

Lastly in the way of substantive remarks, applicant was asked about the commercial product NORMOCARB in the previous Office action. Although applicant states in his 5/19/2005 reply that NORMOCARB is a registered Trademark belonging to the assignee of this application, applicant provides no

[2] It is noted that claim 10 is not included in this ground of rejection. The Examiner believes that picking and choosing both the calcium free feature and magnesium concentration feature (Mg = 0.75 ± 0.07 mmol/l) is not fairly suggested from Martis' disclosure as a whole and Martis' specific disclosure of 0-4 mEq/l calcium and 0-4 mEq/l magnesium.

technical information as to the product or its composition content. Applicant mentions a registration printout~~, but such a printout cannot be located in the record of this case~~. Notwithstanding such a printout, applicant is reminded of his duty of disclosure under 37 CFR § 1.56. The duty to disclose "all information known to be material to patentability" in this application must include NORMOCARB product information, including product content, technical information, and *relevant* public disclosure, public use, and on sale activity, **if** (1) a product named NORMOCARB is readable on or similar to any one of applicant's present claims, and (2) such product was known, disclosed, in public use in this country, on sale in this country, or otherwise placed into or as prior art within the purview of 35 USC § 102.

(Printout found). JP 8/8/05

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machines is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner John Pak whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Mr. Gary Kunz, can be reached on **(571)272-0887**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number **is (571) 272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have a question on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
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GROUP 1600